EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	)	CASE NO: 1:19-md-02875-RBKJS
THIS DOCUMENT RELATES TO: In Re: Valsartan, Losartan and Irbesartan Products Liability Litigation.	)	

(VOLUME II)
HIGHLY CONFIDENTIAL REMOTE VIDEOTAPED DEPOSITION
OF LAURA M. PLUNKETT, Ph.D.
FRIDAY, FEBRUARY 10, 2023
9:04 CENTRAL TIME

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TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before LYDIA F. McDONNELL, a Certified Shorthand Reporter and Notary Public of the State of New Jersey, held remotely from Houston, Texas, on Friday, February 10, 2023, commencing at 9:04 a.m. Cental Time

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(All appearances remote via Zoom conference.)
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ALSO PRESENT:
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I N D E X

THE VIDEOGRAPHER: We are going on the record at 9:04 Central Time on February 10th, 2023. This is Media Unit No. 1 of the video-recorded continuation deposition of Dr. Laura Plunkett regarding the Valsartan litigation.

All counsel will be noted on the stenographic record.

Would the court reporter please swear in the witness, and then we can begin.

L A U R A M. P L U N K E T T, Ph.D., doing business at 13923 Carriage Rock Lane, Houston, Texas, 77336, having been duly sworn by the Notary Public, testified as follows:

MR. VAUGHN: Jessica, before we begin, just on the record, we agreed we have a one-hour limit between the three Defendants.

MS. MILLER: Correct.

MR. VAUGHN: Awesome. Thank you. Go ahead.

CONTINUED REDIRECT EXAMINATION BY MS. MILLER:

Q. Hi, Dr. Plunkett. Good to see you again. I know it's been a while, but do you recall saying at your last deposition when you were being questioned by Plaintiff's counsel that if at any point in time Valsartan contained NDMA, it would be

de- -- or NDEA, it would be deemed adulterated?

A. I don't remember the exact question, but I certainly do have an opinion. I think it's consistent with something that I have stated in my report as well.

Q. And right before I was cut off, I asked you who you believed would deem Valsartan adulterated, and you said -- and I'm quoting from your -- from the transcript -- "I would deem it adulterated consistent with the FDA's actions that they took and a decision that they made in 2019 when they sent the warning letter and made that statement." Do you recall that?

A. Again, not the exact language, but I think that's true. I would -- I would stand by that testimony, yes.

Q. So -- so you --

A. I wouldn't change that.

Q. So you agree that adulteration is a finding that's made by the FDA.

MR. VAUGHN: Object to form.

A. In terms of an official regulatory finding, yes. The FDA would make that finding; however, like in this litigation, or any litigation that I've served in, as an expert dealing with

compliance with FDA regulations, it is certainly something that I -- I have in the past, and have formed an opinion on that, I believe consistent with the regulation and consistent with FDA's own finding that the product is -- would be deemed adulterated.

Q. And the FDA made that finding with respect to ZHP's API in the warning letter, correct?

MR. VAUGHN: Object to form.

A. Yes. I -- well, I don't -- it may be in other places, but certainly, it is in the warning letter, yes.

Q. Did you see any other places where the FDA made a finding that ZHP's API -- scratch that.

Did you see any other document in which the FDA used the term "adulterated" or "adulteration" with respect to ZHP's API?

MR. VAUGHN: Object to form.

A. I'd have to go and look to answer that fully. I don't recall. It's possible that it is discussed on some of the documents on the FDA website that are -- that deal with issues related to the recall, but I'd have to look. I don't recall.

Q. Are you aware of any statement the FDA said suggesting, or otherwise referencing adulteration or adulterated with respect to ZHP's API

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prior to the November 2018 warning letter?
MR. VAUGHN: Object to form.
A. Based on the evidence I've seen, I can't answer that without looking, but I would be surprised if they did because, again, when FDA put -- makes that determination, it's regulatory finding that would trigger a warning letter typically, or some official action. Adulteration is one of those standards that would be triggered -- one of those things that would trigger an actual -- either an untitled letter, but most likely a warning letter, being issued to the company. So I -- I -- that's where I would expect to see it when FDA makes that statement.
Q. Okay. That was a long roundabout answer. I just want to make sure I understand. You are not aware of the FDA making any finding or statement prior to the warning letter of November 2018 suggesting or stating that ZHP's API was adulterated, correct?
MR. VAUGHN: Object to form.
A. And I'd answer the same way: I can't answer that fully without looking based on the fact that you're giving it a specific date; however, as I state- -- I -- I tried to point out to you that I

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would expect to find it in official documents, like a warning letter, because that is typically where I see such statements or decisions discussed.
Q. Okay. I'm a little confused by your answer, because my question was are you aware of, not was there. And so I just want to clarify. You are not aware of any such finding, statement or suggestion prior to November 2018, correct?
MR. VAUGHN: Object to form.
A. And I'd answer the same way: I said I can't answer that fully without looking, but I was trying to explain to you that if -- if it did exist, it would be in something like another warning letter. I don't recall, and I'd have to go look in the files to see if there's anything else.
Q. Sitting here today, you're not aware of such -- of any such statement or suggestion by the FDA, correct?
A. Without --
MR. VAUGHN: Object to form.
A. Without looking, that is correct. I'd have to go back and look at the documents; that's correct.
Q. And you're also not aware of any statement issued by the FDA suggesting that ZHP

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failed to comply with CGMP prior to the November 2018 warning letter, correct?
MR. VAUGHN: Object to form.
A. I need to ask you to clarify. Can I ask for a clarification of that question? Because I think it's a little un- -- it's a little ambiguous. Can -- you want me to explain what I'm -- why I'm confused?
Q. Sure.
A. So are you saying that -- are you limiting this to the fact that FDA never made a determination that there was a lack of compliance with GMP except in a letter that is dated in 2018 even though it may also reference things that happened before 2018, or are you saying that -- are you saying that -- are you doing something else? If that's what you're answering -- if that's what you're asking, I think that's a little more clear, and I can answer that question.
Q. I am asking whether you are aware of any statements made by the FDA before the warning letter in November 2018 in which the FDA suggested or stated that ZHP had failed to comply with CGMP?
MR. VAUGHN: Object to form.
Q. It's a very simple question.

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A. It's really not so simple because they can be in a warning letter where they made a statement re: referencing actions or activities that predate --
Q. I didn't ask that.
A. -- a statement, but certainly --
Q. I'm asking about the date of a statement. Are you aware of any statement made by FDA before November 2018? That's the question I'm asking. You can answer --
MR. VAUGHN: Object to form.
Q. -- another question to Brett.
MR. VAUGHN: Argumentative.
Q. My question is, are you aware of a statement made by FDA before November 2018 in which FDA suggested or stated that ZHP had been in violation of CGMP?
MR. VAUGHN: Object to form. Argumentative. Asked and answered.
A. So I -- I can't answer that question without looking as well, because now I'm -- I'm thinking as I listen to your question, are you only limiting it to Valsartan and that API? Then that's a little easier question to answer.
Again, there's -- there's multiple times

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that FDA has interacted with the -- ZHP, but if you're talking about specific to the issue of Valsartan and the CGMPs for Valsartan, is that what you're asking?
Q. That is what I'm asking.
A. I'd have to go look. I can't answer that to say for sure, but certainly, they did do that in 2018; that is correct.
Q. Sitting here today, can you point to any statement or suggestion made by the FDA before November 2018 regarding ZHP's compliance with CGMP with respect to Valsartan?
MR. VAUGHN: Object to form.
A. So I'd answer the same way: I'd have to go look. I can't answer that without looking to see if there is another document, but certainly, they do do that in the 2018 document.
Q. But you can't point right now without looking to any other document. Is that correct?
MR. VAUGHN: Object to form. Argumentative.
A. Not without looking, I -- I cannot name you another document; that is true. But again, I -- I can't say that there is not such a document.
Q. Do you ever recall seeing such a

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document?
MR. VAUGHN: Object to form.
A. I have -- I don't recall ever asking the question of the doc- -- I don't recall ever assessing the documents the way you're asking the question, so that's why I'm -- I'm -- I'm stating it the way I am. It's not that I went about review of the documents to look for a statement specific -- as specific as you are asking it.
I'm not the -- I'm not the only one dealing with the issues related to GMP, so it's very possible there are other letters that are in the documents that I've looked at that I just don't remember, because they're not ones that I state to -- I don't cite to in my report, for example, in terms of the description of my opinion.
Q. Do you consider yourself to be offering a CGMP opinion in this litigation?
A. I'm not the CGMP expert in terms of all of the details of the CGMP inspections compliance, that is, I believe, Dr. Bain in the litigation, but I certainly have expertise around the issues of the importance of CGMP as described in my report to complying fully and as it relates to the issue of adulteration.

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Q. Are you or are you --
A. How important the CGMP standard is to that.
Q. Are you or are you not offering an opinion about ZHP's compliance with CGMP?
A. From the aspect as stated in my report, I am giving you an opinion as it relates to the issue of how CGMP ties to the adulteration standard, yes, but I did not do the full analysis on my own of all of the documents related to the GMP issues. Again, that's in the scope of Dr. Bain, so I'd suggest that that's where you would go to ask a lot of the questions you may have about the documents in that area.
Q. So you're offering an opinion about CGMP, but you don't know whether FDA ever addressed ZHP's compliance with CGMP with respect to Valsartan before the November 2018 warning letter.
MR. VAUGHN: Object to form. Compound. Argumentative.
A. So I'm saying I'd have to go back and look at the documents. I don't recall. That's all I'm stating for you. Because in my report, if you look at what I address as it relates to the statement, I point to the 2018 letter.

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Q. Do you point to anything else?
A. In my report as stated, no. But what I'm telling you, I did have access to a variety of other documents. And as you're asking the question, I'd have to go back and look to see whether or not any of the other documents that I have seen or that have been attached as exhibits to depositions that I have reviewed indeed address your point.
Q. If the FDA had addressed adulteration or CGMP violations with respect to Valsartan before November '18, wouldn't you have included that in your report?
MR. VAUGHN: Object to form.
A. It depends.
Q. What does it depends on?
A. It depends upon the -- how the evidence related in terms of the opinions -- the -- the way that -- the information I've reviewed, the opinions that I've expressed. I don't recall that document, but as I always do in my deposition, if you have one, show it to me. I don't recall it, but I can't say for sure that I have ruled out that there's nothing there because that was beyond the scope of what I did. Looking for and reviewing and having at the tip of my memory everything that I -- that I have

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reviewed, there are other documents there. They looked and did other GMP inspections in the past. Where the GM- -- where the Valsartan line was, indeed, operating at ZHP. I don't recall a document, that's what I think I've told you already. But I can't -- in order to fully answer and say absolutely, there is no such document, I'd have to go look.

I don't know how else to -- to answer the question for you in order to be accurate in terms of what my memory is and what the -- the breadth of the information that is available to me.

Q. Are you offering an opinion on whether the FDA made any statements regarding adulteration or CGMP violations with respect to ZHP's Valsartan API before November 2018?

A. About their statement? No. Because I -- that is not in my report. What I cite to in my report is the 2018 statement.

Q. So you do not have an opinion as to whether or not that was the first time the FDA offered a statement or suggestion regarding adulteration or CGMP with respect to API -- ZHP? You don't have --

MR. VAUGHN: Object to form.

A. I have not formed that opinion as you're

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asking it, no. And in order to verify one way or the other for you, I'd have to go and look.

Q. And you don't recall that. Sitting here today, you don't recall whether that's the first time or not.

MR. VAUGHN: Object to form.

A. I can't tell you without looking accurately, whether that is, indeed, the first time. I -- I certainly am aware that -- that that is a time that's highly relevant in this case, and I have discussed it and described it in my report.

MS. MILLER: Steve, she's all yours.

RECROSS-EXAMINATION BY MR. HARKINS:

Q. Good morning, Dr. Plunkett. How are you doing?

A. Fine. Thank you.

Q. I would like to follow up on a few things from the end of your deposition.

As a reminder in case you've forgotten, I represent the Teva Defendants, one of the finished-dose manufacturers in this case. You're aware of that, right?

A. Yes.

Q. You just testified a little bit about the warning letter that was directed to ZHP with

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Ms. Miller, correct?

A. Yes.

Q. You're aware that the FDA has never sent a warning letter to Teva related to their Valsartan finished-dose drug product.

A. So I can't verify that by the research that I have done. In other words, I haven't looked at all of the warning letters that have come in, for example, what might have happened after the warning letter from 2018, but I can't -- I certainly have not referred to one, and I have not formed an opinion about any warning letters to Teva after 2018 'cause I don't cite to them in my report. Does that answer your question?

Q. You're -- you're not aware of any warning letter like the one that was sent to ZHP that was sent to Teva related to their finished-dose Valsartan drug product. Is that correct?

A. I have not seen such a warning letter; that is true.

Q. Are you aware of any public statement by FDA or finding related to Teva's finished-dose drug product being adulterated?

MR. VAUGHN: Object to form.

A. Are you being broad as far as public

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statements? And the reason I ask that is so, for example, at the FDA website where they discuss the recall, they're listed as a product that's been recalled, and it's listed as being recalled because of the presence of the NDMA. And we know that the presence of the NDMA is what triggered the adulteration finding by the government, by -- by FDA, so that evidence exists. But maybe you're meaning something more specific, so....

Q. I -- I -- I think I am. Let me try and help.

I understand your opinion with regard to adulteration. I am asking if you are aware -- and I am being broader than just a warning letter -- of any public statement by the FDA specifically that Teva's finished-dose drug product was adulterated.

MR. VAUGHN: Object to form.

A. Okay. So do you -- you -- are you asking me do they use the -- a specific set of words or.... because I do think in the -- I'd have to go pull them. I have some of them printed out here like I had at the first deposition. I'd have to go back and look at the statements from the FDA website over time because they mention API from Teva, from Torrent. From a variety of different manufacturers.

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Not API --
Q. I am being --
A. -- finished dose. Finished-dose product.
Q. I am being specific to Teva's finished-dose drug product and the actual term "adulteration" as set forth in the Food, Drug and Cosmetics Act, if you are aware of any public statement, including on those statements that you are referencing, declaring that Teva's finished-dose Valsartan drug product was adulterated.
A. I'd have to go look to see the exact terms they use, but I would argue -- not argue. I would point out to you that the fact that the product was "recall" was evidence of, and linkage to that finding of adulteration. That's what led to the recall. And their product, indeed, is stated in the doc- -- in different public documents to have been subject to the recall.
But if you are looking for a specific sentence that says FDA sent a warning letter saying that Teva had an adulterated product or FDA found Teva's product to be adulterated, those specific words, I'd have to go and look. I don't know. But basically, to me, as a regulatory expert, the issue

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is they were recalled. It is stated they were part of the recall, and -- and the evidence shows and the facts of the case show, that that recall was linked to the finding of adulteration in the API.
Q. Dr. Plunkett, you're not aware, as you sit here today, without reviewing additional material, of any such statement. Is that fair?
MR. VAUGHN: Object to form.
A. I'm not aware of those specific words as you're asking, but I'm trying to point out to you that regardless of whether those words are used, the fact that the public documents describe Teva's product as part of the recall, that there is essentially linking those to the issue of adulteration. That was the reason for the recall, so I don't think you can walk away from that. Their product would be -- because of the recall, their product is also adulterated because of the fact that it contains the -- the ZHP API.
Q. Dr. Plunkett, I'm not asking or -- or -- or requesting that you change your opinion that I understand as to whether you believe the product was adulterated; I'm just trying to confirm, are you aware, as you sit here today, of any public statement that specifically indicates Teva's Valsartan

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finished-dose product was adulterated?
MR. VAUGHN: Object to form.
A. And I'd have to answer it the exact same way: The way you're asking -- if -- if you're asking me that specific phrase, I'd have to go and look in the public statements, but how -- what I'm pointing out to you is regardless of whether those specific words are there is -- the product is what it is. It's an adulterated product that was included in the recall.
Q. And Dr. Plunkett, I am not asking you to speculate on documents that you haven't seen. Without going and reviewing additional documents, as you sit here today, you are not aware of that specific statement with respect to Teva's Valsartan finished-dose drug product, correct?
MR. VAUGHN: Object to form.
A. I am not aware of those specific words; that is correct. But again, I think that there's context here that is important to understand, and that's all I'm trying to point out to you. Is that the con- -- the -- the use of those words is -- is -- is one thing, but there's also the understanding of what the recall was based on, which we know there are many -- there's a variety of public statements from

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Teva themselves about them recalling their product.
Q. Understood. Dr. Plunkett, is, in your opinion, that every product that is recalled is adulterated under the FD&C Act?
A. No. There's different reasons for recall, if that's what you're asking me. Adulteration -- adulterated products are often subject to recall, but there's -- you know, I -- I wouldn't say it's at 100 percent all the time that they would be recalled. It would depend whether there's anything to recall, No. 1. And then there's other reasons to recall besides adulteration.
Misbranding, for example, is a reason to potentially recall if the FDA makes the decision that the issues related to the misbranding are serious enough to raise a safety concern for the public.
Illegally -- illegally selling a product that is a -- another example would be illegally selling a product that is making drug claims, which isn't regulated as a drug could be subject to a potential recall as well. There's a variety of different ways.
Q. And just to confirm, there -- there are other different ways. Those aren't specifically the things that are at issue in this case, correct?

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MR. VAUGHN: Object to form.
A. That is -- based on the recall that is at issue in this case; that is true. It is around an adulteration issue.
Q. Now, in -- in addition to issuing a warning letter, the FDA has any number of other enforcement mechanisms that it can take when it deems a product to be adulterated or otherwise inappropriately present on the market. Is the right?
MR. VAUGHN: Object to form.
A. If you're asking me generally about their --
Q. Generally, yeah.
A. -- mobilities, yes. Generally they have a variety of enforceabilities; that is true.
Q. They could seize adulterated product in coordination with DOJ. Is that right?
A. If it got raised to that level, yes. It typically doesn't happen unless the company refuses first to cooperate.
Q. They can issue consent decrees. They can do import alerts. Those type of things?
A. Import alerts, absolutely. Those are a very -- that happens all the time. That's actually a pretty easy thing to do. But the -- the issues

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related to seizures, those kinds of things, those are things that typically don't happen unless there's been some -- in my experience, there's been some lack of cooperation for the -- on a -- by a company to cooperate in terms of taking care of the issue.
Q. And they can take a number of actions after an FDA inspection. They could take a -- something like an Official Action Indicated if they find problems at the facility?
MR. VAUGHN: Object to form.
A. Are you asking is that possible for FDA to do? If that's what you're asking, yes, that -- there are different things that FDA can do.
Q. Yes, no. That's -- that's what I'm asking generally. They could also take a Voluntary Action Indicated after inspection of a facility as well generally.
MR. VAUGHN: Object to form.
A. By "they" do you mean the company, or by "they" do you mean --
Q. I mean FDA.
A. Oh, FDA. They can ask for vol- -- oh, sure. They can ask a company or they can inquire or write to a company and ask for voluntary action. Is that what you're asking?

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Q. Yes.
A. Yeah, that's correct. It can be a voluntary. And -- and typically, most recalls are voluntary, again, because most companies will cooperate when an issue is identified and brought to their attention.
Q. And as we know from this case, they can send a warning letter to a company, right?
MR. VAUGHN: Object to form. Vague. As too vague.
A. Well, it depends.
Q. Sorry. If the FDA sends a warning letter. Let me correct the question, Dr. Plunkett.
MR. VAUGHN: I was trying to help.
Q. If FDA --
MR. HARKINS: Sorry. I understood the objection. Withdrawn.
Q. FDA can obviously send a warning letter to a company, correct?
A. A company that it regulates as it relates to a product; yes, that's correct. If it -- if it has -- if FDA is -- if a company has a product under the purview of FDA, yes, FDA can send a warning letter.
Q. And as you sit here today, you're not

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aware of FDA taking a single one of these enforcement steps with respect to Teva and their Valsartan finished-dose drug product, are you?
MR. VAUGHN: Object to form.
A. Well, certainly, recall they did. Is that what you're asking me? There was a recall that was asked for. But are you asking me about seizures and junctions, import alerts? What are you asking?
Q. Other than the voluntary recall that Teva initiated in coordination with FDA, are you aware of any other official action like any of those we just described taken by FDA with respect to Teva's Valsartan finished-dose drug product?
MR. VAUGHN: Object to form.
A. I -- off the top of my head, I am not aware -- or I couldn't name one for you. But again, I can't -- I can't -- I can't with 100 percent surety say that such doesn't exist somewhere. I just -- I'm not aware of it. That's the best way I can answer it for you.
Q. Understood. At the end of your deposition last time, you discussed the finished-drug manufacturer obtaining access to the closed portion of the DMF for API referenced in its ANDA. Do you recall that testimony?

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A. In general terms we did; yes, that's correct.
Q. You cannot identify any section of the Code of Federal Regulations that requires a finished-dose manufacturer to obtain access to the DMF for API referenced in its ANDA?
MR. VAUGHN: Object to form.
A. Off the -- no. But again, the -- the FDA regulations as they exist are a -- a floor, a ceiling, a minimum set. I am aware of the fact 'cause I've worked with companies before that go to someone when they're going to be considering them as a supplier and asking for an NDA or a confidentiality agreement to review in detail files that relate to a process, so it can be done.
Q. Again, I --
A. But that -- but I would agree with you. I don't -- I don't believe there -- any of the regulations address that specifically.
Q. And similarly, you cannot identify any CGMP that requires a finished-dose manufacturer to obtain access to the DMF for API referenced in its ANDA, correct?
MR. VAUGHN: Object to form.
A. Well, the CGMP regulations are more

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broad than that. That would be a pretty prescriptive step to be asking that someone to do -- or asking to be in the regulations, but I would argue that -- or not -- I don't want to argue. I would point out that the CGMP regulations require that a finished-dose manufacturer have processes in place, a good quality system, management system in place to ensure that their product is being manufactured and produced consistent with GMPs. That's part of that as we talked about in some detail, I believe. I don't think it may have been with you. It may have been with Ms. Miller back -- back in January on the first day.
Those quality system requirements or those quality systems include the -- the fact that the finished-dose manufacturer has to have appropriate processes in place to ensure that their drug, indeed, is being produced consistent with GMP.
Q. And -- and I think you may have answered my question at the beginning, but just to confirm. I am not asking about broader quality system issues; I am just trying to confirm that there is no specific prescription under CGMPs requiring a finished-drug manufacturer to obtain access to the DMF in order to reference API in its ANDA, correct?

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A. Yes. I answered that, and I said yes, that I -- I am not aware of that. And the reason is, first off, the regulations are not that prescriptive; however, there is guidance around this issue and the guidance that FDA has -- has produced indicates that. That's what I'm referring to, is the idea that there's an expectation, and actually a -- the -- the regulations broadly require that a finished-dose manufacturer take all steps necessary to ensure that the product they're selling is consistent and in compliance with CGMP.
Q. Dr. Plunkett, I'm gonna go ahead and just Screen Share a section of the CFR here. We can introduce this as an exhibit as well. Are you familiar with this regulation?
A. Yes. If you want to talk about a specific section, I'll -- I'll -- we'll need to review it.
Q. Understood. And this is cited in your Reliance list. I think generally under 21 CFR DMF. Is -- is this what you're referring to there?
A. Yes. This is part of it. This is just one page of it. But yes, that's correct.
Q. Understood. And I'm happy to upload this and let you have any time to review it if you

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need, but looking just down under the first part here on subsection A. Do you see that?
A. I see section -- yes. I see that section, yes.
MR. VAUGHN: Steve, do you mind uploading it just so I can review the full document as well.
MR. HARKINS: Yeah. And this has been into the -- popped in the Dropbox.
Is the videographer on to add this to an exhibit? I think we're on the Novak Trial Services platform today.
MR. VAUGHN: That's the one I'm on.
THE VIDEOGRAPHER: Yes. It -- it should be in there now.
MR. HARKINS: I'm up- -- re-uploading it now. Give me one second.
(Exhibit-12, 21 CFR 314.420, marked for identification.)
THE WITNESS: Can I ask a question? This will be Exhibit -- a new exhibit that -- you're gonna make this Exhibit-12. Is that correct?
MR. HARKINS: Yes. It will be a new exhibit.
THE WITNESS: Okay.

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MR. HARKINS: And do you have access to the Dropbox, Dr. Plunkett?
THE WITNESS: I -- well, I don't think I need it for this document. It's two pages. I'm generally familiar with what's here. Ask your question. I may need you to go to page 2. But if you're on Part A, I can see it, so go ahead -- right ahead and ask your question.
MR. VAUGHN: I'm good to go, Steve. And I've got it pulled up now.
MR. HARKINS: Great.
Q. All right. And Dr. Plunkett, if you need any time or questions about the document, just let me know.
Looking under subpart A, and I'm asking to start with the -- it is the phrase after the colon "purposes." If you're able to see it here.
A. Yes, I see it. "To permit the holder."
Q. And go ahead and just read that sentence into the record.
A. "To permit the holder to incorporate the information by reference when the holder submits an investigational new drug application under part 312 or submits an application or an abbreviated application or an amendment or supplement to them

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under this part, or to permit the holder to authorize other persons to rely on the information to support a submission to FDA without the holder having to disclose the information to the person."
Q. And -- and I'm happy to -- if you want to qualify this: Generally speaking, this is the description in the CFR of the purpose of Drug Master Files?
A. Yes, that's correct.
Q. And in that language that you just read, the holder in this case would be the DMF holder or the API manufacturer. Is that correct?
MR. VAUGHN: Object to form.
A. It would be -- this is the DMF holder, and obviously the DMF holder could be more than an API manufacturer. But yes, an API manufacturer in this case was the Drug Master File holder; that is true.
Q. And when it says "other persons to rely on the information," those other persons would be finished-dose manufacturers from, for example, another company, correct?
MR. VAUGHN: Object to form.
A. Well, I think they're pretty broad, but that generally would be who I would be expecting that

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other person to be, yes.
Q. And understanding it might be broader, but in this case, for example, that would be Teva and Torrent as the finished-dose manufacturers referencing ZHP's Valsartan API DMF. Is that right?
A. Yes. But I'm a- -- I'm aware of the fact that they did; that is correct. And that -- that relationship is true based upon the way you've described it.
Q. And just to return to one of your statements about the regulation, are you aware of any FDA guidance, and again, that requires a finished-dose manufacturer to obtain access to the DMF for API referenced in its ANDA?
MR. VAUGHN: Object to form.
A. State the first part of your sentence again?
Q. I -- I believe you've indicated -- 'cause I had asked some questions about whether there was anything in the CFR or in GMPs as to whether there was anything that specifically required a finished-dose manufacturer to either seek or obtain access to API -- sorry -- to the DMF for its API. My question is, can you identify any FDA guidance that requires a finished-dose manufacturer to obtain

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access to the DMF for API referenced in its ANDA?
A. So I think -- I -- I think you're asking something other than the way I'm hearing it, 'cause I would say to you, this regulation specifically is requiring them to reference it obviously. If they're going -- if they're gonna be permitted to -- if they're -- if they're gonna be permitted to reference it, this is the way they would do it, I guess is what I'm saying, but I think you're asking something else.
I -- I think what you're -- maybe I'm wrong, but I think where you're going -- maybe you need to reask the question 'cause I'm not really sure what you're trying to ask in terms of the -- because this particular -- this particular part of the language would, indeed, state what the holder should be doing in terms of referencing the DMF.
Q. And -- and just to be clear -- and maybe this is two questions. First, Dr. Plunkett, this regulation does not require an ANDA applicant to obtain access to the closed portion of the DMF, correct?
A. Oh. That's a different -- okay. I didn't hear "closed portion" in your other question. That's why I was confused.
Okay. So yes; that is correct. It does

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not require them to access the closed portion; that is true. This is not there.
Q. And --
A. But again, there's other -- there's other regulations or other guidance that I was talking about when I was referencing that issue.
Q. And that is my question. Are you aware of any guidance from FDA that requires an ANDA applicant to obtain access to the closed portion of a DMF?
MR. VAUGHN: Object to form.
A. I think I answered that for you earlier. I said I don't recall -- I don't -- I don't think there's a specific language to the regulation to require it in the way you're stating it; however, they do require compliance of GMPs. And if the only way to ensure compliance, in my view, for example, in this case, is to understand the details on whether or not the company making the API has -- is complying with those GMPs having done the full risk assessment and all those things, I don't know how you do that without getting into some of the closed portion of the -- of the Drug Master File.
But I -- that's -- that's -- I don't think that's what you're asking me, so I tried to

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answer it first. I don't believe there's specific language the way you are stating it, but that doesn't mean the finished-dose manufacturer doesn't have an obligation under the law, the regulations and also as set forth in the guidance to take steps to ensure that their drug that they're selling, their finished dose is, indeed, in compliance with GMP.
Q. Well, maybe -- let me try and break that down a little bit.
You don't cite to any document in your report which identifies a requirement for a finished-dose drug manufacturer to obtain access to the closed portion of a DMF, do you?
A. I don't state an -- an opinion that way. No, I don't. If that's what you're asking me. I don't have a statement that proactively states exactly what you did; however, I have opinions that are relevant to answering that question.
Q. Understood. And I just want to be clear. You don't identify any document on your Reliance list which requires a finished-dose manufacturer to obtain access to the closed portion of a DMF, do you?
A. There's not, no. But again, it -- what -- what is the step there, as I discuss in my

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report, is the regulations for the finished-dose manufacturer that are applicable which would require them to take the steps they need to take to ensure that their product is being manufactured consistent with GMPs which, in my view, could include access to the closed portion. And in my experience working with companies, that's what companies have done.
Q. So I just want to clarify. Is it your opinion that any finished-dose manufacturer who does not obtain access to the closed portion of the DMF violation of CGMPs?
A. No. I'm not implying that. That's a broader statement than I think I -- I have stated. Do you want me to explain?
Q. Maybe I can clarify. I understand it is your opinion in this case that the finished-dose manufacturers should have done that. Is it your opinion that any finished-dose manufacturer who does not also manufacture the API needs to obtain access to the closed portion of the DMF in order to comply with CGMP?
MR. VAUGHN: Object to form.
A. I think that is not an opinion -- opinion that I have formed at this time, no. However, I would couch that by saying that it's

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probably most important. I might have that -- that opinion if you added the clause, in cases where the API manufacturer is using a process that is -- that is different than the process that was part of the listing of the monograph for the referenced listed drug.
Q. Okay. So with that qualification, then, is it your opinion that any finished-dose manufacturer who does not obtain access to the DMF violation of CGMP or that DMF, does not use the same manufacturing process as the referenced listed drug?
MR. VAUGHN: Object the form.
A. I would -- I would -- I would say that that -- it -- that could be an issue, yes; that's correct. I mean, I think I would couch that with, it could. Because I -- it would really depend on the circumstances and the conditions.
Certainly, the regulations do not put out the requirement the way -- I think I've agreed with you on that. I -- the regulations don't make it an absolute requirement for the company to take that step, but as I've tried to explain, that the issue in this case is different. The issue in this case -- and I -- I think I have formed the opinion, and I don't want to go back over that again, but

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essentially you know what my opinion is. I do believe, in this case, they should have done that.
Q. And I'm gonna go ahead and take that down. And if for any reason you need to see that again, Dr. Plunkett, let me know.
Dr. Plunkett, at the end of your deposition last time, you also testified that the finished-dose manufacturers, including Teva, should have done what Novartis did to identify the NDMA impurity. Do you recall that testimony?
A. I don't know exactly how I stated it, but I certainly do -- do believe that -- that as -- as -- I think what I stated was we know that a finished-dose manufacturer did do it, so it could have been done. And certainly, that would have been something that would have made sense for these companies to do. They didn't do it. But certainly, they could have, and I believe they should have.
Q. Have you reviewed documents to determine how Novartis identified, and then structurally characterized, the NDMA in Valsartan API?
MR. VAUGHN: Object to form. Foundation.
A. I have re- -- I have reviewed deposition testimony that talks about some of the internal

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documents that have gone back and forth on this issue. I'm -- surely -- I'm sure I have not seen every document, because I don't believe Novartis discovery is available in this case, so I haven't seen a bunch of Novartis files. But certainly, I am aware of some documents and some discussion, and -- and those that I have seen indicated, generally, the steps that Novartis took.
Q. So -- and hearing your counsel's objection on foundation, I understand if you don't know the answers to these questions. And if that's the case, please let me know.
Novartis did not identify the potential for NDMA formation based on analysis of the Valsartan API chemical route of synthesis as documented in the DMF, did they?
MR. VAUGHN: Object to form.
A. I can't answer that, actually, without looking. I can't answer that. I don't know.
Q. And Novartis did not identify the potential for NDMA formation as part of a risk assessment it prepared on the Valsartan API, did they?
MR. VAUGHN: Object to form. Foundation.

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A. I can't answer that either without looking. I don't know. I don't know whether that's addressed in the documents I have seen.
Q. And sitting here, you don't know either way, do you?
A. Without --
MR. VAUGHN: Object to form.
A. Without looking at the documents that I know describe it, I don't recall that discussion of why it was done. It's my understanding they were looking for new -- here's what I do know. I -- it was my understanding that Novartis was looking to qualify as a new supplier. I don't know for what purpose generally. I don't know whether, you know, they had an ANDA at issue. I don't know those details because I don't have a lot of discovery documents from Novartis that describes their motivation.
Q. And again, one way or another, do you know whether Novartis identified, and then structurally characterized, NDMA using a theoretical analysis of the route of synthesis?
MR. VAUGHN: Object to form.
A. So that's beyond the scope of what I looked at, although I do believe that that is

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described in other experts' reports. Maybe the chemist's --
Q. And --
A. -- report. I'm not sure.
Q. And -- and just to say, Dr. Plunkett, you don't know specifically how or why Novartis eventually identified the NDMA in Valsartan API, do you?
MR. VAUGHN: Object to form.
A. Well, I -- I can't -- I don't know -- if you're asking why, I'm not in Novartis's head, so I can't answer that. As far as what, I'm -- there's a description of what they did, but I -- again, that was beyond the scope of, I think, my -- of what I did in terms of the opinions I formed because, to me, that's more of an issue of -- maybe for the chemist to describe what -- what they did in terms of the methods they used, things like that.
Q. And I -- I think I understand. How Novartis eventually identified and structurally characterized NDMA is not part of the opinions that you're offering in this case, correct?
A. That is true, that is not. I believe that -- that may be someone else, but that's not me.
Q. And therefore, your opinion that the

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finished-dose manufacturers, including Teva, should have done the same thing that Novartis did is only based on the fact that you understand Novartis eventually structurally characterized NDMA. Is that fair?

MR. VAUGHN: Object to form.

A. I don't think I can answer that yes or no. Can I explain or -- or can I ask you to clarify?

Q. Let me try and ask a better question.

I -- I understand it's your opinion that Teva and Torrent should have identified it based on the fact that Novartis did. Is that fair?

A. Novartis could, that's right, and they did; yes, that's correct.

Q. But you don't know how Novartis actually structurally characterized and identified NDMA.

A. Without going to look, I can tell you, some of that is described. It talks about the methods they used. That's in some of the documents, but that was beyond the scope of, I think, what I was asked to do in this case.

I was not asked to, for example, determine whether or not the chemical methods that Novartis used were better or worse or -- you know, I -- I mean, that -- that is all -- I think that's

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sort of where -- where that goes, and so that's why I'm hesitant to say anything more than what I've already said. I think it is beyond the scope of what I did. But I do know that there are documents that I have reviewed that describe some of the -- the details on how they did it.

Q. And the specifics of that are beyond the scope of your opinions in your report, correct?

A. In terms of the opinions I had formed; yes, that's correct. It wasn't -- it was not in -- it was not something that I -- that I covered because it's my -- in my view, that would be an issue for a chemist to cover, for example, or someone else may have been asked to do that, but that wasn't something I was asked to do.

MR. HARKINS: Thank you, Dr. Plunkett. Those are all the questions that I have for you today. I believe counsel for Torrent is gonna have some follow-up as well.

MR. VAUGHN: Thanks, Steven.

RECROSS-EXAMINATION BY MS. NAGEL:

Q. Good morning, Dr. Plunkett. Do you remember we spoke a few weeks ago during the first part of your deposition?

A. Yeah. I think you just asked a couple

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of questions. You were very short, but yes, I do recall.

Q. I did not have much time. And you -- you recall I represent the Torrent Defendants, correct?

A. Yes.

Q. Dr. Plunkett, in your Materials Relied Upon list, you list just shy of 30 documents that were produced by Torrent, and one transcript from a Torrent employee, correct?

A. I don't know the exact number, but that's probably true, yes. I think there's only one transcript, that's for sure. I don't know if -- if 30 is accurate. But yes, there's certainly many, many more documents with a ZHP Bates number on there -- or Bates identifier on there.

Q. Okay. And as part of that small set of documents that you reviewed for Torrent, you reviewed the -- some of the technical and quality agreements between Torrent and ZHP, correct?

MR. VAUGHN: Object to form.

A. Certainly, some of those documents that I have reviewed and relied upon are quality agreements, yes. There's a paragraph in my report where I think I cite to those.

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Q. And the quality agreement establishes what parts of the DMF are gonna be shared with Torrent, correct?

MR. VAUGHN: Object to form.

A. I don't know if that's addressed. I -- I believe the quality agreement -- the part that I talk about talks about who's respons- -- who's responsible for what, but if you want me to pull it up.... I can't answer that without looking.

Q. Dr. Plunkett, you didn't actually review the parts of the DMF that were shared with Torrent, did you?

MR. VAUGHN: Object to form. Argumentative.

A. I did not review the entire Drug Master File; that is correct. And I -- and I can't tell you which parts were shared, so -- without -- so I don't think I have information to answer that. I don't think I can answer that.

Q. Okay. And Dr. Plunkett, what documents did you rely on in forming -- or what Torrent documents did you rely on in forming your opinion that Torrent should have obtained full access to ZHP's DMF?

A. Well, I don't think I'm necessarily

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relying on Tor- -- well, I'm relying on the -- the documents that -- that show that Torrent and ZHP had an agreement to -- to exchange -- to set -- they had an -- they had an agreement to buy product from ZHP. So that part of the -- the agreement ties them together as -- as the supplier for the finished-dose manufacturer.

Beyond that, my opinions that I have expressed are based upon the regulatory requirements for -- as a finished-dose manufacturer to ensure that their product is compliant with GMP, the -- and my experience and training.

And then I think, as I have said, as I just discussed with Mr. Harkins as it relates to Teva, those -- those same opinions would hold. It's the idea that what regulations put the onus on the finished-dose manufacturer for the product they sell. The guidance describes, in fact, that the finished-dose manufacturer is supposed to take steps to validate the -- the product that comes from their supplier routinely. It's not something that only is done once. It has to be done continually over time to -- to make sure -- to ensure that the product remain as it did the first day they moved -- shipped the batch that they initial- -- they initially may

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have used for their initial validation exercise, so they have other responsibilities.

So I think the majority of my opinions would -- the majority of the information that I have relied upon to form that opinion would be based upon the general regulation, my experience and training, as well as them -- the agreement that shows that the two parties were, indeed, engaged in a relationship of an API being bought from ZHP and that Torrent was the finished-dose manufacturer and the holder of the ANDA.

Q. So to confirm, you're not relying on any documents -- any Torrent documents that establish what information Torrent had from the DMF in forming that opinion, correct?

MR. VAUGHN: Object to form.

A. I don't know. I mean, I'd have to go back and look if any of the documents that I have discuss that. That's why I think I started -- when you asked the question before this one, I think I said I'd have to -- I don't know. I'd have to look whether or not the quality agreement addresses that specific issue. I can't answer that without looking.

Q. And Dr. Plunkett, I believe you testified a few minutes ago that you did not review

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ZHP's DMF or what parts were made available to Torrent. Is that right?

A. I said I -- I think I -- I think what I said was I did not review the entire DMF. I did not. And I'm not -- and also, right as I sit here, I'm not aware of any document that tells me exactly what they were made -- what was made available to them. But certainly, that is -- I have seen discussions of their ability to be able to reference the DMF. So again, I can't answer your question fully without looking at the Torrent documents I have. I don't recall one, though.

MS. NAGEL: Okay. Mr. Vaughn, can I have like five minutes?

MR. VAUGHN: For a break?

MS. NAGEL: Yes, please.

MR. VAUGHN: Yeah, Of course.

THE VIDEOGRAPHER: The time is 9:55. We're going off the record.

(Break: 9:55 a.m. Central Time.)

(Resume: 10:01 a.m. Central Time.)

THE VIDEOGRAPHER: The time is 10:01. We're back on the record.

MS. NAGEL: So Dr. Plunkett, that is all the questions I have for you, and I think Defendants

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are just going to reserve the remainder of their time for any recross.

MR. VAUGHN: I have no questions, so I think we're done.

THE VIDEOGRAPHER: Great. The time is 10:01. This ends today's deposition.

(Proceedings concluded at 10:01 a.m. Central Time.)

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J U R A T

I, LAURA M. PLUNKETT, Ph.D. DO HEREBY CERTIFY that I have read the foregoing transcript of my deposition testimony.

_____

LAURA M. PLUNKETT, Ph.D.

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DAY OF_____
2023

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DATE TAKEN: Friday, February 10, 2023

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Rule 30

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